K120120
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510(K) SUMMARY

MAR 15 2012

Submitter:	AGA Medical Corporation 5050 Nathan Lane Plymouth, MN
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Date Prepared:	January 13, 2012
Trade Name:	AMPLATZER® TorqVue® 45°x45° Delivery Sheath AMPLATZER® TorqVue® LA1 Delivery Sheath AMPLATZER® TorqVue® LA2 Delivery Sheath
Common Name:	Catheter Delivery System
Classification:	Class II, 21 CFR 870.1250 Catheter, Percutaneous
Product Code:	DQY
Predicate Device(s):	AMPLATZER TorqVue 45°x45° Delivery Sheath (K083214)

Device Description: The AMPLATZER TorqVue LA and AMPLATZER TorqVue 45x45 Delivery Sheaths are general purpose delivery sheaths designed to access and deliver a device to the chambers of the heart. The TV45x45 Delivery Sheath is curved approximately 45° in two dimensions resulting in a three-dimensional geometry. The TVLA1 provides a single 45° curve on the distal end of the sheath. The TVLA2 provides the same 45° curve as the TVLA1 with a second superior curve at the distal tip of 20-30°.

The sheaths are offered in five sizes each (9Fr, 10Fr, 12Fr, 13FR, and 14Fr). The TVLA sheaths and are 80 cm in length and the TV45x45 sheath is 100 cm in length.

The devices include a sheath to enable device delivery, a dilator to ease entrance into and through the vasculature, and a flush adaptor for the 10, 12, 13, and 14Fr sizes to enable connection with syringes for flushing the sheath lumen. The sheaths and dilators are radiopaque for visibility under fluoroscopy. For added visibility, the sheaths also have a radiopaque marker band near the distal tip.

Intended Use: The AMPLATZER TorqVue 45°x45°, LA1, and LA2 Delivery Sheaths are intended to provide a pathway through which devices are introduced within the chambers of the heart.

Comparison to predicate:

The predicate device, the TV45x45, is currently marketed under K083214 clearance for the 9, 10, 12, and 13Fr sizes. Design changes were made to the predicate, which included:

14Fr TV45x45 Delivery Sheath

- Addition of larger sheath size
- Change to flush adapter (14Fr devices only)
- Addition of additional backing card to packaging (14Fr devices only)

TVLA Delivery Sheaths

- Addition of larger sheath size
- Change to device length
- Change to sheath distal curve geometry
- Change to flush adapter (14Fr devices only)
- Addition of additional backing card to packaging (14Fr devices only)

Functional and Safety Testing:

Bench and laboratory testing was performed to support a determination of substantial equivalence to the predicate device. Results from the testing show the proposed device conforms to the requirements for its intended use. This included the following testing:

- Dimensional Tests
- Trackability Test
- Kink Test
- Flushability Test
- Handoff / Advancement Force Test
- Recapture Force Test
- Visual Inspection Post-Interaction Testing
- Sheath Tip Tensile Test
- Sheath Transition Tensile Test
- Sheath Surface Inspection
- Sheath torque to failure
- Dilator Hub Tensile Test
- Sheath Hub Tensile Test
- Sheath Luer Leak Test (water and air)
- Design validation testing (animal study)

Conclusion:

AGA Medical Corporation considers the 14Fr AMPLATZER TorqVue 45°x45° Delivery Sheath, 9-14Fr AMPLATZER TorqVue LA1 Delivery Sheaths, and 9-14Fr AMPLATZER TorqVue LA2 Delivery Sheaths to be substantially equivalent to the predicate device listed above. This conclusion is based upon the devices' similarities in principles of operation, technology, materials and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAR 15 2012

AGA Medical Corporation
c/o Rashmi Bhushan, Ph.D.
Principal Regulatory Affairs Specialist
5050 Nathan Lane
Plymouth, MN 55433

Re: K120120
Trade/Device Name: AMPLATZER® TorqVue® 45°x45° Delivery Sheath
AMPLATZER® TorqVue® LA1 Delivery Sheath
AMPLATZER® TorqVue® LA2Delivery Sheath
Regulation Number: 21 CFR 870.1250
Regulation Name: Catheter, Percutaneous
Regulatory Class: Class II
Product Code: DQY
Dated: February 22, 2012
Received: February 23, 2012

Dear Dr. Bhushan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K120120

Device Name: AMPLATZER TorqVue 45°x45° Delivery Sheath
AMPLATZER TorqVue LA1 Delivery Sheath
AMPLATZER TorqVue LA2 Delivery Sheath

Indications for Use: The AMPLATZER TorqVue 45°x45°, LA1, and LA2 Delivery Sheaths are intended to provide a pathway through which devices are introduced within the chambers of the heart.

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K120120